IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#16 Election w/attach. 6.10.03

In re Patent Application of

SCHREIBER

Serial No. 09/913,159

Filed: August 10, 2001

For: VIRAL VACCINE

Atty. Ref.: 35-213

Group: 1648

Examiner: HILL

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June 4, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE

Responsive to the Official Action dated February 4, 2003, the applicants respectfully traverse the restriction requirement and request withdrawal of the same in view of the following.

Contrary to the Examiner's assertions, the applicants respectfully submit that unity of invention exists for the presently claimed invention. The Examiner is urged to appreciate that the present application is a U.S. National Phase of PCT/EP99/095759, such that the principles of unity of the invention apply.

The applicants acknowledge, with appreciation, the Examiner issuing the Office Action of February 4, 2003, and vacating the Office Action of December 3, 2002.

The applicants respectfully submit that the basis for the Examiner's assertion that unity of invention does not exist, i.e., based on Tartar, et al. (FR2677363), is unfounded.

Specifically, the applicants submit that the vaccine composition of Tartar, et al. does not teach randomly distributed sequence combinations. That is, Tartar, et al. is understood by the applicants to start from patient isolates, as can be seen from pages 5 and 6 of FR2677363. For example, in the second paragraph on page 5 of the reference, the following is stated:

"Selon l'invention il est proposé, notamment dans le cas de la production d'une composition vaccinante qui mettrait en jeu la partie centrale hypervariable de la région V3 de la gp120, de produire une composition essentiellement constitué d'un mélange (faisceau), de peptides parmi lesquels des peptides susceptibles d'induire la formation chez l'homme ou l'animal d'anticorps reconnaissant des épitopes spécifiques de variants de retrovirus HIV, caractérisée en ce qu'elle contient la quasi totalité des séquences découlant de toutes les combinaisons possibles qui peuvent être rêalisée entre les acides aminés successifs respectivement sélectionnés un a un dans les colonnes successives 1 à 26 de la formule globale ci-dessous indiquée"

[English translation:

"According to the invention it is proposed, in particular in the case of the production of a vaccinating composition which would bring into play the central hypervariable part of the V3 region of the gp120, to produce a composition primarily made up of a mixture (group) of peptides, among which peptides suitable for inducing in the human or animal the formation of antibodies

recognizing the specific epitopes of the variants of the retrovirus HIV, characterized in that it contains almost exclusively sequences resulting from all possible combinations, which can be realized between the respective successive amino acids selected one by one in the successive columns 1 to 26 of the general formula indicated below."]

It is clear to the applicants from this passage that Tartar, et al. teach a mixture of peptides which may induce in the subject to be treated antibodies which recognize specific epitopes of HIV variants. It is clear to the applicants from the use of the term "épitopes spécifiques de variants de retrovirus HIV" (specific epitopes of the variants of the retrovirus HIV) that Tartar, et al. refer to only those variants which are already known in the art. This is further supported by the peptide formula shown at the top of page 6, of the cited reference which shows a generic formula of the peptides within a consecutive sequence of 26 amino acid positions. From this formula it is clear to the applicants that each of the positions allows only a limited number of amino acids to be chosen. For example, positions 1 and 2 are restricted to the amino acid asparagin, whereas at position 8,6 different amino acids are possible. However, the fact that for each of these 26 amino acid positions only a very limited number of amino acids are possible does not provide a random distribution of sequence combinations as does the presently claimed invention. In contrast, according to the instantly claimed invention, for each of the amino acid positions which are varied, all 20 naturally occurring amino acids are possible.

In summary, the applicants submit that the "random distribution" is the special technical feature within the Examiner's Group I, which defines a contribution over the cited art. Contrary to the Examiner's assertion, the technical features of the Examiner's Groups II-VIII are drawn to methods having the same goals, method steps and starting materials, which do require each other for their practice and do share the same or a corresponding technical feature. Because the technical feature of the Examiner's Group I is a special technical feature, and because the technical features of the Examiner's Group II-VIII are also present in the Examiner's Group I, unity of invention should be acknowledged. Withdrawal of the restriction requirement and examination of all the claimed subject matter are requested.

In order to be responsive only, the applicants elect the Examiner's Group II (claims 4-22, 26-28, 30-37, 49, and 50-52), drawn to DNA vaccine, without prejudice. Reconsideration and withdrawal of the restriction requirement are requested along with an early and favorable Action on the merits.

Respectfully submitted,

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